

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: September 13, 2012
ATTENTION: Members, Executive Committee
SUBJECT: Emergency Contraception

RECOMMENDED ACTION:

Review the revised Emergency Contraception (EC) Protocol regulations to ensure amendments requested by the Medical Board of California (Board) were made.

BACKGROUND AND ANALYSIS:

Pharmacists may furnish emergency contraception medications based on a statewide protocol adopted by the California State Board of Pharmacy (BOP) and the Medical Board of California (MBC) (Section 4062.3(a)(2) of the California Business and Professions Code). Pharmacists may use the protocol after they have completed one hour of continuing education credit in emergency contraception.

On January 6, 2012, the BOP initiated a rulemaking to amend the Emergency Contraception Protocol to reflect updates in emergency contraception products. The board received one comment. At its meeting held May 1, 2012, the BOP rejected the one comment received but, in the weeks that followed, received information on a new two-tablet regimen. The BOP decided to propose modifications to the protocol to reflect this new regimen, as well as to clarify the dosing instructions in the table of Dedicated Approved Products for Emergency Contraception. The BOP approved the issuance of modified text at its July 2012 meeting, pending approval by the MBC.

At its July 2012 board meeting, the MBC considered the comment received during the 45-day comment period, as well as the BOP's proposed modifications to the table of Dedicated Approved Products for Emergency Contraception. The MBC concurred with the proposed modifications, and also made additional changes. The additional amendments requested by MBC included striking language regarding insertion of an IUD, telling the patient to consult with a healthcare provider for other options to EC, and to follow-up with a healthcare provider after EC.

The BOP will consider the MBC's amendments at its October 2012 board meeting. If approved, the BOP will issue the modified language for a 15-day public comment period. A copy of the proposed modified text is attached.

The Executive Committee Members should review the attached language to ensure it is compliant with the MBC amendments.

Board of Pharmacy Modified Language

To Amend § 1746 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section ~~4052(a)(8)~~ 4052.3(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

~~(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to the protocols specified in Business and Professions Code section 4052.3. Use of the following protocol satisfies that requirement.~~

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication ~~within required limits~~ and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and state communicate the following:

Are you allergic to any medications?

Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) ~~of after~~ after unprotected intercourse. ~~EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.~~

MODIFIED TEXT FOR CONSIDERATION

Page 1 of 6

Modified language approved by the Board of Pharmacy July 17, 2012, are shown as follows:

Deleted text is shown by double strike-through, thus: ~~deleted language~~

New or added text is shown by double underline, thus: added language

Changes to the Modified Language approved by the Medical Board of California on July 19, 2012, are shown as follows:

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EC use will not interfere with an established or implanted pregnancy.

If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. ~~For other options for EC~~

include consultation with your health care provider physician regarding insertion of an IUD.

Please follow up with your health care provider after the use of EC.

(4) The pharmacist shall provide the a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section ~~4052(b)(3)~~ 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication ~~compatible with product information~~ from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

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(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in ~~the~~ this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

~~(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.~~

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(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Dedicated Emergency Contraception

Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One-Dose Regimen				
Plan-B	Women's Capital Corporation	2 tablets	0	1.5
Two-Dose Regimens				
Plan-B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynetics	2 tablets per dose	100	0.50
Oral Contraceptive Pills				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart*)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

* The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel

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(11) Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception

<u>Brand</u>	<u>Dose</u>	<u>Ethinyl Estradiol</u> <u>per dose (mcg)</u>	
<u>One Tablet Dose Regimen</u>			
<u>Plan B™ One-Step</u>	<u>1 tablet</u>	<u>0</u>	<u>1.5mg</u> <u>levonorgestrel</u>
<u>ella™</u>	<u>1 tablet</u>	<u>0</u>	<u>30mg ulipristal</u>
<u>Levonorgestrel</u>	<u>1 tablet</u>	<u>0</u>	<u>1.5mg</u> <u>levonorgestrel</u>

<u>Two Tablet Dose Regimens</u>			
<u>Next Choice™</u>	<u>2 tablets at once</u> <u>(1.5mg total dose)</u> <u>or</u> <u>1 tablet (0.75mg) followed by</u> <u>1 tablet (0.75mg) 12 hours later</u> <u>1 tablet per dose</u>	<u>0</u>	<u>Each tablet is</u> <u>0.75 mg</u> <u>1.5mg</u> <u>levonorgestrel</u>
<u>Levonorgestrel</u>	<u>2 tablets at once</u> <u>(1.5mg total dose)</u> <u>or</u> <u>1 tablet (0.75mg) followed by</u> <u>1 tablet (0.75mg) 12 hours later</u>	<u>0</u>	<u>Each tablet is</u> <u>0.75 mg</u> <u>levonorgestrel</u>

Oral Contraceptive Pills

<u>Brand</u>	<u>Tablets per Dose</u> <u>(two doses 12 hours apart*)</u>	<u>Ethinyl Estradiol</u> <u>per dose (mcg)</u>	<u>Levonorgestrel</u> <u>per dose (mg)*</u>
<u>Alesse</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Aviane</u>	<u>5 orange tablets</u>	<u>100</u>	<u>0.50</u>
<u>Levlen</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>
<u>Levlite</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Levora</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Lo/Ovral</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.50</u>
<u>Low-Ogestrel</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Nordette</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>

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<u>Ogestrel</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Ovral</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Tri-Levlen</u>	<u>4 yellow tablets</u>	<u>100</u>	<u>0.50</u>
<u>Triphasil</u>	<u>4 yellow tablets</u>	<u>120</u>	<u>0.50</u>
<u>Trivora</u>	<u>4 pink tablets</u>	<u>120</u>	<u>0.50</u>
<u>Ovrette</u>	<u>20 yellow tablets</u>	<u>0</u>	<u>0.75</u>

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

(12) Anti-nausea Treatment Options for use with Emergency Contraception

Anti-Nausea Treatment Options For Use With Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; Repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP <u>EC</u> dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code. Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code.

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